SUMMONS ISSUED

FILED
IN CLERK'S OFFICE
U.S. DISTRICT COURT E.D.N.Y.
★ DEC 10 2010 ★
BROOKLYN OFFICE

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK
--X
KRISTINE ESPOSITO,

Plaintiff,

-against-

XANODYNE PHARMACEUTICALS, INC.

Defendant.
--X

Civil Action No.

CV 10 5737

COMPLAINT

WEINSTEIN, J.
POHORELSKY, M.J.

Plaintiff, by her attorneys, **PARKER WAICHMAN ALONSO LLP,** on behalf of herself individually, upon information and belief, at all times hereinafter mentioned, alleges as follows:

JURISDICTION

1. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332, because the amount in controversy as to the Plaintiff exceeds $75,000.00, exclusive of interest and costs, and because Defendant, XANODYNE PHARMACEUTICALS, INC. is incorporated and has its principal places of business in states other than the state in which the named Plaintiff resides.

2. This Court has supplemental jurisdiction over the remaining common law and state claims pursuant to 28 U.S.C. § 1367.

3. Venue is proper in this Court pursuant to 28 U.S.C. § 1391 because a substantial part of the events giving rise to Plaintiff's claims occurred, in part, in the Eastern District of New York.

NATURE OF THE CASE

4. This action is brought on behalf of Plaintiff, KRISTINE ESPOSITO, who was prescribed, purchased and correctly used DARVOCET, also known generically as Propoxyphene Napsylate and Acetaminophen.

5. Defendant, XANODYNE PHARMACEUTICALS, INC (hereinafter referred to as "Defendant") designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed DARVOCET for use as a prescription pain management medication.

6. Defendant concealed their knowledge of DARVOCET's defects, from Plaintiff, the FDA, the public in general and/or the medical community specifically.

7. When warning of safety and risks of DARVOCET, Defendant negligently and/or fraudulently represented to the medical and healthcare community, the Food and Drug Administration (hereinafter referred to as "FDA"), to Plaintiff and the public in general, that DARVOCET had been tested and was found to be safe and/or effective for its indicated use.

8. These representations were made by Defendant with the intent of defrauding and deceiving Plaintiff, the public in general, and the medical and healthcare community in particular, and were made with the intent of inducing the public in general, and the medical community in particular, to recommend, dispense and/or purchase DARVOCET for use as a prescription pain management medication, all of which evinced a callous, reckless, willful, depraved indifference to health, safety and welfare of the Plaintiff herein.

9. Defendant negligently and improperly failed to perform sufficient tests, if any, concerning DARVOCET's potential to cause cardiotoxicity and, more specifically, potentially fatal cardiac arrhythmias, during clinical trials, forcing Plaintiff, and her physicians, hospitals,

and/or the FDA, to rely on safety information that applies to other prescription pain management medications, which does not entirely and/or necessarily apply to the DARVOCET whatsoever.

10. As a result of the defective nature of DARVOCET, those persons who use and/or used and relied on DARVOCET have suffered and/or are at a greatly increased risk of serious and dangerous side effects including, including, inter alia, heart arrhythmias, myocardial infarction, other adverse cardiovascular events and/or sudden death, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

11. Plaintiff herein has sustained certain of the above health consequences due to her use of DARVOCET.

12. Defendant concealed its knowledge of the defects in its product from the Plaintiff, and her physicians, hospitals, pharmacists, the FDA, and the public in general.

13. Consequently, Plaintiff seeks compensatory damages as a result of her use of DARVOCET, which has caused, may cause, and/or will continue to cause Plaintiff to suffer and/or be at greatly increased risk of serious and dangerous side effects including, including, inter alia, heart arrhythmias, myocardial infarction, other adverse cardiovascular events and/or sudden death, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

PARTY PLAINTIFF

14. Plaintiff, KRISTINE ESPOSITO, is a natural person and is a resident of the State of New York.

15. Prior to February 2010, plaintiff, KRISTINE ESPOSITO, did not have a pre existing cardiac history and had never suffered a cardiac arrhythmia.

16. Plaintiff, KRISTINE ESPOSITO, was prescribed DARVOCET for pain management in or about February 2010.

17. As result of using Defendant's drug DARVOCET, Plaintiff KRISTINE ESPOSITO, was caused to suffer cardiovascular injuries and cardiac arrhythmias, including but limited to, wide complex tachycardia in or about February 2010.

18. Plaintiff, KRISTINE ESPOSITIO used DARVOCET in the manner in which it was prescribed to her at or about the time she suffered cardiovascular injuries and arrhythmias, including but limited to, wide complex tachycardia, in or about February 2010.

19. In order to treat her arrhythmia and life threatening cardiac condition, plaintiff, KRISTINE ESPOSITO, underwent painful electrocardioversion and numerous other invasive cardiac procedures including cardiac ablation.

20. Plaintiff, KRISTINE ESPOSITO, was caused to sustain severe, permanent and life threatening personal injuries, pain, suffering, emotional distress, lifelong fear of premature death and the need for continued lifelong cardiac monitoring, treatment and medications.

21. The injuries and damages sustained by Plaintiff, KRISTINE ESPOSITO, were caused by Defendant's drug DARVOCET.

PARTY DEFENDANT

22. Upon information and belief, Defendant XANODYNE HARMACEUTICALS, INC., and at all relevant times was and is a corporation organized under the laws of the State of Kentucky, with its principal place of business located in the State of Kentucky.

23. Upon information and belief, at all relevant times Defendant XANODYNE PHARMACEUTICALS, INC., has transacted and conducted business in the State of New York and derived substantial revenue from interstate commerce.

24. Upon information and belief Defendant XANODYNE PHARMACEUTICALS, INC., expected or should have expected that its acts would have consequences within the United States of America, and Sunnyside, New York and within the confines of the Eastern District of New York in particular and derived substantial revenue from interstate commerce.

25. Upon information and belief, and at all relevant times Defendant XANODYNE PHARMACEUTICALS, INC., was in the business of and did design, research, manufacture, test, advertise, promote, market, sell and distribute DARVOCET for use as a prescription management medication

26. Upon information and belief, Defendant XANODYNE HARMACEUTICALS, INC., is the holder of approved New Drug Application for DARVOCET.

FACTUAL BACKGROUND

27. At all relevant times, Defendant was and remains in the business of and did design, research, manufacture, test, advertise, promote, market, sell, distribute, and/or have recently acquired the Defendant who have designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed DARVOCET for use as a prescription pain management medication.

28. At all times relevant, defendant focused its sales on pain management products including DARVOCET because the area of pain management offers attractive commercial opportunities in significant markets in the United States, see http://www.xanodyne.com/strategy.asp (as of December 9, 2010).

29. At all times relevant, defendant affirmatively decided not to take part in full discovery research of its products because defendant believed that it was more beneficial for it to advance products quickly through abbreviated developmental pathways in order to decrease the time and cost of bringing a new drug to market, see http://www.xanodyne.com/strategy.asp (as of December 9, 2010).

30. By using a strategy of moving its products through the research and development process expeditiously defendant believes it can reach its goal of becoming a leading integrated specialty pharmaceutical company that develops and commercializes new products for significant markets in pain management, http://www.xanodyne.com/strategy.asp (as of December 9, 2010).

31. About 10 million people in the U.S. received prescriptions for DARVOCET and Propoxyphene related drugs, in 2009 according to the FDA.

32. Upon information and belief, Adverse Event data maintained by the FDA indicates staggering, serious Adverse Events, including, heart arrhythmias, atrial fibrillation, tachycardia, bradycardia, myocardial infarction, and/or sudden death.

33. Defendant ignored the correlation between the use of DARVOCET and the increased risk of developing potentially fatal heart arrhythmias, despite the wealth of scientific and medical evidence available.

34. In June 2009, the European Medicines Agency (EMEA) recommended that the marketing authorizations for Propoxyphene be withdrawn across the European Union for safety concerns.

35. Despite being petitioned by public interest groups to investigate whether DARVOCET was linked to serious and potentially fatal heart arrhythmias, Defendant refused to do so until July 2009, when it was ordered by the FDA to conduct a safety study assessing unanswered questions about the effects of DARVOCET on the heart.

36. Plaintiff, KRISTINE ESPOSITO, experienced a near fatal cardiac arrhythmia as a result of taking DARVOCET in February 2010.

37. The results of the study order by the FDA indicated that even when taken at recommended doses, Propoxyphene causes significant changes to the electrical activity of the heart. These changes, which can be seen on an electrocardiogram (ECG), can increase the risk for serious abnormal heart rhythms that have been linked to serious adverse effects, including sudden death.

38. On November 19, 2010, the FDA announced that defendant, Xanodyne Pharmaceuticals, Inc., had agreed to halt all U.S. Marketing of DARVOCET after it was

determined that the drugs benefits were outweighed by the risks associated with its use, specifically the potential of the drug to cause serious and potentially fatal heart arrhythmias.

39. The use of DARVOCET creates unique and dangerous risks compared to other prescription pain management medications. These risks include, including inter alia heart arrhythmias, myocardial infarction, and other adverse cardiovascular events, including sudden death.

40. The Defendant did not provide adequate warnings to doctors, the health care community and the general public about the increased risk of serious adverse events that are described herein and that have been repeated by the medical community.

41. By reason of the foregoing, Plaintiff has developed and/or is at extremely high risk of serious and dangerous side effects including, including, inter alia, heart arrhythmias, myocardial infarction, other adverse cardiovascular events and/or sudden death, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

42. Plaintiff has endured and continue to suffer the mental anguish and psychological trauma of living with the knowledge that she has and/or may suffer serious and dangerous side effects including, inter alia, heart arrhythmias, myocardial infarction, other adverse cardiovascular events and/or sudden death, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

43. By reason of the foregoing, Plaintiff has been severely and permanently injured, including the risk of premature death, and will require more constant and continuous medical monitoring and treatment than prior to her use of Defendant's drug DARVOCET.

FEDERAL REQUIREMENTS

44. Defendant had an obligation to comply with the law in the manufacture, design, and sale of DARVOCET.

45. Upon information and belief, Defendant violated the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §301, *et seq.*

46. With respect to the prescription drug DARVOCET, the defendant, upon information and belief, has or may have failed to comply with all federal standards applicable to the sale of prescription drugs including, but not limited to, one or more of the following violations:

a. The prescription drug DARVOCET is adulterated pursuant to 21 U.S.C. § 351 because, among other things, it fails to meet established performance standards, and/or the methods, facilities, or controls used for its manufacture, packing, storage or installation is not in conformity with federal requirements. See, 21 U.S.C. § 351.

b. The prescription drug DARVOCET is adulterated pursuant to 21 U.S.C. § 351 because, among other things, its strength differs from or its quality or purity falls below the standard set forth in the official compendium for DARVOCET and such deviations are not plainly stated on their labels.

c. The prescription drug DARVOCET is misbranded pursuant to 21 U.S.C. §352 because, among other things, its labeling is false or misleading.

d. The prescription drug DARVOCET is misbranded pursuant to 21 U.S.C. §352 because words, statements, or other information required by or under authority of chapter 21 U.S.C. § 352 are not prominently placed thereon with such conspicuousness and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

e. The prescription drug DARVOCET is misbranded pursuant to 21 U.S.C. §352 because the labeling does not bear adequate directions for use, and/or the labeling does not bear adequate warnings against use where its use may be dangerous to health or against unsafe dosage or methods or duration of administration or application, in such manner and form as are necessary for the protection of users.

f. The prescription drug DARVOCET is misbranded pursuant to 21 U.S.C. §352 because it's dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof.

g. The prescription drug DARVOCET does not contain adequate directions for use pursuant to 21 CFR § 201.5, because, among other reasons, of omission, in whole or in part, or incorrect specification of (a) statements of all conditions, purposes, or uses for which it is intended, including conditions, purposes, or uses for which it is prescribed, recommended or suggested in their oral, written, printed, or graphic advertising, and conditions, purposes, or uses for which the drugs are commonly used, (b) quantity of dose, including usual quantities for each of the uses for which it is intended and usual quantities for persons of different ages and different physical conditions, (c) frequency of administration or application, (d) duration or administration or application, and/or (d) route or method of administration or application.

h. The Defendant violated 21 CFR § 201.56 because the labeling was not informative and accurate.

i. The prescription drug DARVOCET is misbranded pursuant to 21 CFR § 201.56 because the labeling was not updated as new information became available that caused the labeling to become inaccurate, false, or misleading.

j. The Defendant violated 21 CFR § 201.57 by failing to provide information that is important to the safe and effective use of the drug including the potential of DARVOCET cause and the need for regular and/or consistent cardiac monitoring to ensure that a potential fatal cardiac arrhythmia has not developed.

k. The Defendant violated 21 CFR § 201.57 because they failed to identify specific tests needed for selection or monitoring of patients who took the prescription drug DARVOCET.

l. The Defendant violated 21 CFR § 201.57 because the safety considerations regarding the prescription drug DARVOCET are such that the drug should be reserved for certain situations, and the Defendant failed to state such information.

m. The prescription drug DARVOCET is mislabeled pursuant to 21 CFR § 201.57 because the labeling fails to describe serious adverse reactions and potential safety hazards, limitations in use imposed by it, and steps that should be taken if they occur.

n. The prescription drug DARVOCET is mislabeled pursuant to 21 CFR § 201.57 because the labeling was not revised to include a warning as soon as there was reasonable evidence of an association of a serious hazard with the drug.

o. The Defendant violated 21 CFR § 201.57 because the labeling failed to list the adverse reactions that occur with the prescription drug DARVOCET and other drugs in the same pharmacologically active and chemically related class.

p. The Defendant violated 21 CFR § 201.57 because the possibility that a patient could develop Cardiac Arrhythmia after significantly more severe than the other reactions listed in the adverse reactions, and yet the Defendant failed to list the development of Cardiac Arrhythmia before the other adverse reactions on the labeling of the prescription drug DARVOCET.

q. The prescription drug DARVOCET is mislabeled pursuant to 21 CFR § 201.57 because the labeling does not state the recommended usual dose, the usual dosage range, and, if appropriate, an upper limit beyond which safety and effectiveness have not been established.

r. The prescription drug DARVOCET violates 21 CFR § 210.1 because the process by which it was manufactured, processed, and/or held fails to meet the minimum current good manufacturing practice of methods to be used in, and the facilities and controls to be used for, the manufacture, packing, or holding of a drug to assure that it meets the requirements as to safety and have the identity and strength and meets the quality and purity characteristic that they purport or are represented to possess.

s. The prescription drug DARVOCET violates 21 CFR § 210.122 because the labeling and packaging materials do not meet the appropriate specifications.

t. The prescription drug DARVOCET violates 21 CFR § 211.165 because the test methods employed by the Defendant are not accurate, sensitive, specific, and/or reproducible and/or such accuracy, sensitivity, specificity, and/or reproducibility of test methods have not been properly established and documented.

u. The prescription drug DARVOCET violates 21 CFR § 211.165 in that the prescription drug DARVOCET fails to meet established standards or specifications and any other relevant quality control criteria.

v. The prescription drug DARVOCET violates 21 CFR § 211.198 because the written procedures describing the handling of all written and oral complaints regarding the prescription drug DARVOCET were not followed.

w. The prescription drug DARVOCET violates 21 CFR § 310.303 in that the prescription drug DARVOCET is not safe and effective for its intended use.

x. The Defendant violated 21 CFR § 310.303 because the Defendant failed to establish and maintain records and make reports related to clinical experience or other data or information necessary to make or facilitate a determination of whether there are or may be grounds for suspending or withdrawing approval of the application to the FDA.

y. The Defendant violated 21 CFR §§310.305 and 314.80 by failing to report adverse events associated with the prescription drug DARVOCET as soon as possible or at least within 15 days of the initial receipt by the Defendant of the adverse drugs experience.

z. The Defendant violated 21 CFR §§310.305 and 314.80 by failing to conduct an investigation of each adverse event associated with the prescription drug DARVOCET, and evaluating the cause of the adverse event.

aa. The Defendant violated 21 CFR §§ 310.305 and 314.80 by failing to promptly investigate all serious, unexpected adverse drug experiences and submit follow-up reports within the prescribed 15 calendar days of receipt of new information or as requested by the FDA.

bb. The Defendant violated 21 CFR §§ 310.305 and 314.80 by failing to keep records of the unsuccessful steps taken to seek additional information regarding serious, unexpected adverse drug experiences.

cc. The Defendant violated 21 CFR §§ 310.305 and 314.80 by failing to identify the reports they submitted properly, such as by labeling them as "15-day Alert report," or "15-day Alert report followup."

dd. The Defendant violated 21 CFR § 312.32 because they failed to review all information relevant to the safety of the prescription drug DARVOCET or otherwise received by the Defendant from sources, foreign or domestic, including information derived from any clinical or epidemiological investigations, animal investigations, commercial marketing experience, reports in the scientific literature, and unpublished scientific papers, as well as reports from foreign regulatory authorities that have not already been previously reported to the agency by the sponsor.

ee. The Bayer Defendants violated 21 CFR § 314.80 by failing to provide periodic reports to the FDA containing (a) a narrative summary and analysis of the information in the report and an analysis of the 15-day Alert reports submitted during the reporting interval, (b) an Adverse Reaction Report for each adverse drug experience not already reported under the Post marketing 15-day Alert report, and/or (c) a history of actions taken since the last report because of adverse drug experiences (for example, labeling changes or studies initiated).

ff. The Defendant violated 21 CFR § 314.80 by failing to submit a copy of the published article from scientific or medical journals along with one or more 15-day Alert reports based on information from the scientific literature.

47. Defendant failed to meet the standard of care set by the above statutes and regulations, which were intended for the benefit of individual consumers such as the Plaintiff, making the Defendant negligent *per se*.

AS AND FOR THE FIRST CAUSE OF ACTION AGAINST THE DEFENDANT
(NEGLIGENCE)

48. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

49. Defendant had a duty to exercise reasonable care in the designing, researching, manufacturing, marketing, supplying, promoting, packaging, sale and/or distribution of DARVOCET into the stream of commerce, including a duty to assure that the product would not cause users to suffer unreasonable, dangerous side effects.

50. Defendant failed to exercise ordinary care in the designing, researching, manufacturing, marketing, supplying, promoting, packaging, sale, testing, quality assurance, quality control, and/or distribution of DARVOCET into interstate commerce in that Defendant knew or should have known that using DARVOCET created a high risk of unreasonable, dangerous side effects, including, inter alia, heart arrhythmias, myocardial infarction, other adverse cardiovascular events and/or sudden death, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

51. The negligence of the Defendant, their agents, servants, and/or employees, included but was not limited to the following acts and/or omissions:

(a) Manufacturing, producing, promoting, formulating, creating, and/or designing DARVOCET without thoroughly testing it;

(b) Manufacturing, producing, promoting, formulating, creating, and/or designing DARVOCET without adequately testing it;

(c) Not conducting sufficient testing programs to determine whether or not DARVOCET was safe for use; in that Defendant herein knew or should have known that DARVOCET was unsafe and unfit for use by reason of the dangers to its users;

(d) Selling DARVOCET without making proper and sufficient tests to determine the dangers to its users;

(e) Negligently failing to adequately and correctly warn the Plaintiff, the public, the medical and healthcare profession, and the FDA of the dangers of DARVOCET;

(f) Failing to provide adequate instructions regarding safety precautions to be observed by users, handlers, and persons who would reasonably and foreseeably come into contact with, and more particularly, use, DARVOCET;

(g) Failing to test DARVOCET and/or failing to adequately, sufficiently and properly test DARVOCET.

(h) Negligently advertising and recommending the use of DARVOCET without sufficient knowledge as to its dangerous propensities;

(i) Negligently representing that DARVOCET was safe for use for its intended purpose, when, in fact, it was unsafe;

(j) Negligently representing that DARVOCET had equivalent safety and efficacy as other prescription pain management medications;

(k) Negligently designing DARVOCET in a manner which was dangerous to its users;

(l) Negligently manufacturing DARVOCET in a manner which was dangerous to its users;

(m) Negligently producing DARVOCET in a manner which was dangerous to its users;

(n) Negligently assembling DARVOCET in a manner which was dangerous to its users;

(o) Concealing information concerning FDA warnings from the Plaintiff in knowing that DARVOCET was unsafe, dangerous, and/or non-conforming with FDA regulations;

(p) Improperly concealing and/or misrepresenting information from the Plaintiff, healthcare professionals, and/or the FDA, concerning the severity of risks and dangers of DARVOCET compared to other prescription pain management medications.

52. Defendant under-reported, underestimated and downplayed the serious dangers of DARVOCET.

53. Defendant negligently compared the safety risk and/or dangers of DARVOCET with other prescription pain management medications.

54. Defendant was negligent in the designing, researching, supplying, manufacturing, promoting, packaging, distributing, testing, advertising, warning, marketing and sale of DARVOCET in that it:

(a) Failed to use due care in designing and manufacturing DARVOCET so as to avoid the aforementioned risks to individuals when DARVOCET was used for prescription pain management;

(b) Failed to accompany their product with proper and/or accurate warnings regarding all possible adverse side effects associated with the use of DARVOCET;

(c) Failed to accompany their product with proper warnings regarding all possible adverse side effects concerning the failure and/or malfunction of DARVOCET;

(d) Failed to accompany their product with accurate warnings regarding the risks of all possible adverse side effects concerning DARVOCET;

(e) Failed to warn Plaintiff of the severity and duration of such adverse effects, as the warnings given did not accurately reflect the symptoms, or severity of the side effects;

(b) Failed to conduct adequate testing, including pre-clinical and clinical testing and post-marketing surveillance to determine the safety of DARVOCET;

(g) Failed to warn Plaintiff, prior to actively encouraging the sale of DARVOCET, either directly or indirectly, orally or in writing, about the need for more comprehensive, more regular medical monitoring than usual to ensure early discovery of potentially serious side effects;

(h) Were otherwise careless and/or negligent.

55. Despite the fact that Defendant knew or should have known that DARVOCET caused unreasonably dangerous side effects, Defendant continued to market, manufacture, distribute and/or sell DARVOCET to consumers, including the Plaintiff.

56. Defendant knew or should have known that consumers such as the Plaintiff would foreseeably suffer injury as a result of Defendant's failure to exercise ordinary care, as set forth above.

57. Defendant's negligence was the proximate cause of Plaintiff's injuries, harm and economic loss which they suffered and/or will continue to suffer.

58. As a result of the foregoing acts and omissions, the Plaintiff was and/or still is caused to suffer and/or are at a greatly increased risk of serious and dangerous side effects including, inter alia, heart arrhythmias, myocardial infarction, other adverse cardiovascular events and/or sudden death, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

59. As a result of the foregoing acts and omissions the Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

60. By reason of the foregoing, Plaintiff has been damaged as against the Defendant in the sum of TEN MILLION DOLLARS ($10,000,000.00).

AS AND FOR THE
SECOND CAUSE OF ACTION
AGAINST THE DEFENDANT
(STRICT PRODUCTS LIABILITY)

61. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

62. At all times herein mentioned, the Defendant designed, researched, manufactured, tested, advertised, promoted, marketed, sold, distributed DARVOCET as hereinabove described that was used by the Plaintiff.

63. That DARVOCET was expected to and did reach the usual consumers, handlers, and persons coming into contact with said product without substantial change in the condition in which it was produced, manufactured, sold, distributed, and marketed by the Defendant.

64. At those times, DARVOCET was in an unsafe, defective, and inherently dangerous condition, which was dangerous to users, and in particular, the Plaintiff herein.

65. The prescription pain management medication, DARVOCET, designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendant was defective in design or formulation in that, when it left the hands of the manufacturer and/or suppliers, the foreseeable risks exceeded the benefits associated with the design or formulation of DARVOCET.

66. The prescription pain management medication, DARVOCET, designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by

Defendant was defective in design and/or formulation, in that, when it left the hands of the Defendant manufacturers and/or suppliers, it was unreasonably dangerous, and it was more dangerous than an ordinary consumer would expect.

67. At all times herein mentioned, DARVOCET was in a defective condition and unsafe, and Defendant knew or had reason to know that said product was defective and unsafe, especially when used in the form and manner as provided by the Defendant.

68. Defendant knew, or should have known that at all times herein mentioned its DARVOCET was in a defective condition, and was and is inherently dangerous and unsafe.

69. At the time of the Plaintiff's use of DARVOCET, DARVOCET was being used for the purposes and in a manner normally intended, namely for pain management.

70. Defendant with this knowledge voluntarily designed its DARVOCET in a dangerous condition for use by the public, and in particular the Plaintiff.

71. Defendant had a duty to create a product that was not unreasonably dangerous for its normal, intended use.

72. Defendant created a product unreasonably dangerous for its normal, intended use.

73. The prescription pain management medication, DARVOCET, designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendant was manufactured defectively in that DARVOCET left the hands of Defendant in a defective condition and was unreasonably dangerous to its intended users.

74. The prescription pain management medication, DARVOCET, designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by

Defendant reached its intended users in the same defective and unreasonably dangerous condition in which the Defendant's drug DARVOCET was manufactured.

75. Defendant designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed a defective product which created an unreasonable risk to the health of consumers and to the Plaintiff in particular, and Defendant is therefore strictly liable for the injuries sustained by the Plaintiff.

76. The Plaintiff could not by the exercise of reasonable care, have discovered DARVOCET's defects herein mentioned and perceived its danger.

77. The prescription pain management medication, DARVOCET, designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendant was defective due to inadequate warnings or instructions as the Defendant knew or should have known that the product created a risk of serious and dangerous side effects including, inter alia, heart arrhythmias, myocardial infarction, other adverse cardiovascular events and/or sudden death, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences and the Defendant failed to adequately warn of said risks.

78. The prescription pain management medication, DARVOCET, designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendant was defective due to inadequate warnings and/or inadequate testing.

79. The prescription pain management medication, DARVOCET, designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by

Defendant was defective due to inadequate post-marketing surveillance and/or warnings because, after Defendant knew or should have known of the risks of serious side effects including, inter alia, heart arrhythmias, myocardial infarction, other adverse cardiovascular events and/or sudden death, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences, and they failed to provide adequate warnings to users or consumers of the product, and continued to improperly advertise, market and/or promote its product, DARVOCET.

80. By reason of the foregoing, the Defendant became strictly liable in tort to the Plaintiff for the manufacturing, marketing, promoting, distribution, and selling of a defective product, DARVOCET.

81. Defendant's defective design, manufacturing defect, and inadequate warnings of DARVOCET were acts that amount to willful, wanton, and/or reckless conduct by Defendant.

82. That said defects in Defendant's drug DARVOCET were a substantial factor in causing Plaintiff's injuries.

83. As a result of the foregoing acts and omissions, the Plaintiff was and still is caused to suffer and/or is at a greatly increased risk of serious and dangerous side effects including, inter alia, heart arrhythmias, myocardial infarction, other adverse cardiovascular events and/or sudden death, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

84. As a result of the foregoing acts and omissions the Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

85. By reason of the foregoing, Plaintiff has been damaged as against the Defendant in the sum of TEN MILLION DOLLARS ($10,000,000.00).

AS AND FOR THE
THIRD CAUSE OF ACTION
AGAINST THE DEFENDANT
(BREACH OF EXPRESS WARRANTY)

86. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

87. Defendant expressly warranted that DARVOCET was safe and well accepted by users.

88. The prescription pain management medication DARVOCET does not conform to these express representations because DARVOCET is not safe and has numerous serious side effects, many of which were not accurately warned about by Defendant. As a direct and proximate result of the breach of said warranties, Plaintiff suffered and/or will continue to suffer severe and permanent personal injuries, harm and economic loss.

89. Plaintiff did rely on the express warranties of the Defendant herein.

90. Members of the medical community, including physicians and other healthcare professionals, relied upon the representations and warranties of the Defendant for use of DARVOCET as prescription pain medication in recommending, prescribing, and/or dispensing DARVOCET.

91. The Defendant herein breached the aforesaid express warranties, as its drug DARVOCET was defective.

92. Defendant expressly represented to Plaintiff, her physicians, healthcare providers, and/or the FDA that DARVOCET was safe and fit for use for the purposes intended, that it was of merchantable quality, that it did not produce any dangerous side effects in excess of those risks associated with other prescription pain management medications, that the side effects it did produce were accurately reflected in the warnings and that it was adequately tested and fit for its intended use.

93. Defendant knew or should have known that, in fact, said representations and warranties were false, misleading and untrue in that DARVOCET was not safe and fit for the use intended, and, in fact, produced serious injuries to the users that were not accurately identified and represented by Defendant.

94. As a result of the foregoing acts and/or omissions the Plaintiff, was and still is caused to suffer and/or is at a greatly increased risk of serious and dangerous side effects including, inter alia, heart arrhythmias, myocardial infarction, other adverse cardiovascular events and/or sudden death, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

95. By reason of the foregoing, Plaintiff has been severely and permanently injured, including the potential of premature death, and will require more constant and continuous medical monitoring and treatment than prior to her use of Defendant's drug DARVOCET.

96. As a result of the foregoing acts and omissions the Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

97. By reason of the foregoing, Plaintiff has been damaged as against the Defendant in the sum of TEN MILLION DOLLARS ($10,000,000.00).

AS AND FOR THE
FOURTH CAUSE OF ACTION
AGAINST THE DEFENDANT
(BREACH OF IMPLIED WARRANTIES)

98. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

99. At all times herein mentioned, the Defendant manufactured, compounded, portrayed, distributed, recommended, merchandized, advertised, promoted and sold DARVOCET and/or have recently acquired the Defendant who have manufactured, compounded, portrayed, distributed, recommended, merchandized, advertised, promoted and sold DARVOCET, for use as a prescription pain management medication.

100. At the time Defendant marketed, sold, and distributed DARVOCET for use by Plaintiff, Defendant knew of the use for which DARVOCET was intended and impliedly warranted the product to be of merchantable quality and safe and fit for such use.

101. The Defendant impliedly represented and warranted to the users of DARVOCET and their physicians, healthcare providers, and/or the FDA that DARVOCET was safe and of merchantable quality and fit for the ordinary purpose for which said product was to be used.

102. That said representations and warranties aforementioned were false, misleading, and inaccurate in that DARVOCET was unsafe, unreasonably dangerous, improper, not of merchantable quality, and defective.

103. Plaintiff, and/or members of the medical community and/or healthcare professionals did rely on said implied warranty of merchantability of fitness for a particular use and purpose.

104. Plaintiff and her physicians and healthcare professionals reasonably relied upon the skill and judgment of Defendant as to whether DARVOCET was of merchantable quality and safe and fit for its intended use.

105. The prescription pain management medication DARVOCET was placed into the stream of commerce by the Defendant in a defective, unsafe, and inherently dangerous condition and the product and accompanying materials were expected to and did reach users, handlers, and persons coming into contact with said products without substantial change in the condition in which they were sold.

106. The Defendant herein breached the aforesaid implied warranties, as its drug DARVOCET was not fit for its intended purposes and uses.

107. As a result of the foregoing acts and omissions, the Plaintiff was and/or still is caused to suffer and/or is at a greatly increased risk of serious and dangerous side effects including, inter alia, heart arrhythmias, myocardial infarction, other adverse cardiovascular events and/or sudden death, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

108. As a result of the foregoing acts and omissions the Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

109. By reason of the foregoing, Plaintiff has been damaged as against the Defendant in the sum of TEN MILLION DOLLARS ($10,000,000.00).

AS AND FOR THE
FIFTH CAUSE OF ACTION
AGAINST THE DEFENDANT
(FRAUDULENT MISREPRESENTATION)

110. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

111. The Defendant falsely and fraudulently represented to the medical and healthcare community, and to the Plaintiff, and/or the FDA, and the public in general, that said product, DARVOCET, had been tested and was found to be safe and/or effective for prescription pain management.

112. The representations made by Defendant were, in fact, false.

113. When said representations were made by Defendant, they knew those representations to be false and it willfully, wantonly and recklessly disregarded whether the representations were true.

114. These representations were made by Defendant with the intent of defrauding and deceiving the Plaintiff, the public in general, and the medical and healthcare community in particular, and were made with the intent of inducing the public in general, and the medical and healthcare community in particular, to recommend, prescribe, dispense and/or purchase said

product, DARVOCET, for use as a means of prescription pain management, all of which evinced a callous, reckless, willful, depraved indifference to the health, safety and welfare of the Plaintiff herein.

115. At the time the aforesaid representations were made by the Defendant and, at the time the Plaintiff used DARVOCET, the Plaintiff was unaware of the falsity of said representations and reasonably believed them to be true.

116. In reliance upon said representations, the Plaintiff was induced to and did use DARVOCET, thereby sustaining severe and permanent personal injuries, and being at an increased risk of sustaining severe and permanent personal injuries, and being at an increased risk of premature death.

117. Defendant knew and was aware or should have been aware that DARVOCET had not been sufficiently tested, was defective in nature, and/or that it lacked adequate and/or sufficient warnings.

118. Defendant knew or should have known that DARVOCET had a potential to, could, and would cause severe and grievous injury to the users of said product, and that it was inherently dangerous in a manner that exceeded any purported, inaccurate, and/or down-played warnings.

119. Defendant brought DARVOCET to the market, and acted fraudulently, wantonly and maliciously to the detriment of the Plaintiff.

120. As a result of the foregoing acts and omissions, the Plaintiff was and still is caused to suffer and/or is at a greatly increased risk of serious and dangerous side effects including, inter alia, heart arrhythmias, myocardial infarction, other adverse cardiovascular events and/or sudden death, as well as other severe and personal injuries which are permanent

and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

121. As a result of the foregoing acts and omissions the Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

122. By reason of the foregoing, Plaintiff has been damaged as against the Defendant in the sum of TEN MILLION DOLLARS ($10,000,000.00).

AS AND FOR THE
SIXTH CAUSE OF ACTION
AGAINST THE DEFENDANT
(FRAUDULENT CONCEALMENT)

123. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

124. At all times during the course of dealing between Defendant and Plaintiff, and/or Plaintiff's healthcare providers, and/or the FDA, Defendant misrepresented the safety of DARVOCET for its intended use.

125. At all times during the course of dealing between Defendant and Plaintiff, and/or Plaintiff's healthcare providers, and/or the FDA, Defendant misrepresented the risk of cardiotoxicity caused by DARVOCET.

126. Defendant knew or were reckless in not knowing that its representations were false.

127. In representations to Plaintiff, and/or Plaintiff's healthcare providers, and/or the FDA, Defendant fraudulently concealed and intentionally omitted the following material information:

(a) that DARVOCET was not as safe as other forms of pain management;

(b) that the risks of adverse events with DARVOCET were higher than those with other prescription pain management medications;

(c) that the risks of adverse events with DARVOCET were not adequately tested and/or known by Defendant;

(d) that Defendant were aware of dangers in DARVOCET, in addition to and above and beyond those associated with other prescription pain management medications;

(e) that DARVOCET was defective, and that it caused dangerous side effects, including but not limited to higher incidence of heart arrhythmias, myocardial infarction, other adverse cardiovascular events and/or sudden death, in a much more and significant rate than other prescription pain management medications;

(f) that patients needed to be monitored more regularly than normal while using DARVOCET;

(g) that DARVOCET was manufactured negligently;

(h) that DARVOCET was manufactured defectively;

(i) that DARVOCET was manufactured improperly;

(j) that DARVOCET was designed negligently;

(k) that DARVOCET was designed defectively; and

(l) that DARVOCET was designed improperly.

128. Defendant was under a duty to disclose to Plaintiff, and her physicians, hospitals, healthcare providers, and/or the FDA the defective nature of DARVOCET, including

but not limited to the heightened risks of an adverse cardiovascular event, such as a heart arrhythmia, myocardial infarction or sudden death.

129. Defendant had sole access to material facts concerning the defective nature of the product and its propensity to cause serious and dangerous side effects, and hence, cause damage to persons who used DARVOCET, including the Plaintiff, in particular.

130. Defendant's concealment and omissions of material facts concerning, inter alia, the safety of DARVOCET was made purposefully, willfully, wantonly, and/or recklessly, to mislead Plaintiff, and their physicians, hospitals and healthcare providers into reliance, continued use of DARVOCET, and actions thereon, and to cause them to purchase, prescribe, and/or dispense DARVOCET and/or use the product.

131. Defendant knew that Plaintiff, and her physicians, hospitals, healthcare providers, and/or the FDA had no way to determine the truth behind Defendant's concealment and omissions, and that these included material omissions of facts surrounding DARVOCET, as set forth herein.

132. Plaintiff, as well as her doctors, healthcare providers, and/or hospitals reasonably relied on facts revealed which negligently, fraudulently and/or purposefully did not include facts that were concealed and/or omitted by Defendant.

133. As a result of the foregoing acts and omissions the Plaintiff was and still is caused to suffer and/or is at a greatly increased risk of serious and dangerous side effects including, inter alia, heart arrhythmias, myocardial infarction, other adverse cardiovascular events and/or sudden death, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of

life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

134. As a result of the foregoing acts and omissions the Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

135. By reason of the foregoing, Plaintiff has been damaged as against the Defendant in the sum of TEN MILLION DOLLARS ($10,000,000.00).

AS AND FOR THE
SEVENTH CAUSE OF ACTION
AGAINST THE DEFENDANT
(NEGLIGENT MISREPRESENTATION)

136. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

137. Defendant had a duty to represent to the medical and healthcare community, and to the Plaintiff, the FDA and the public in general that said product, DARVOCET, had been tested and found to be safe and effective for prescription pain management.

138. The representations made by Defendant were, in fact, false.

139. Defendant failed to exercise ordinary care in the representation of DARVOCET, while involved in its manufacture, sale, testing, quality assurance, quality control, and/or distribution of said product into interstate commerce in that Defendant negligently misrepresented DARVOCET's high risk of unreasonable, dangerous side effects.

140. Defendant breached its duty in representing DARVOCET's serious side effects to the medical and healthcare community, to the Plaintiff, the FDA and the public in general.

141. As a result of the negligent misrepresentations of the Defendant set forth hereinabove, said Defendant knew and were aware or should have known that DARVOCET had been insufficiently tested, and/or had not been tested, that it lacked adequate and/or accurate warnings, and/or that it created a high risk and/or higher than acceptable risk, and/or higher than reported/represented risks, as well as unreasonable, dangerous side effects, including, inter alia, heart arrhythmias, myocardial infarction, other adverse cardiovascular events and/or sudden death, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

142. As a result of the foregoing acts and omissions the Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

143. By reason of the foregoing, Plaintiff has been damaged as against the Defendant in the sum of TEN MILLION DOLLARS ($10,000,000.00).

AS AND FOR THE
EIGHTH CAUSE OF ACTION
AGAINST THE DEFENDANT
(FRAUD AND DECEIT)

144. Plaintiff repeats, reiterates and realleges each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

145. Defendant conducted research and/or had a duty to conduct research using DARVOCET as part of its research.

146. As a result of Defendant's research and testing, or lack thereof, Defendant blatantly and intentionally distributed false information, including but not limited to assuring the public, the Plaintiff, her doctors, hospitals, healthcare professionals, and/or the FDA that DARVOCET was safe and effective for use as a means of pain management.

147. As a result of Defendant's research and testing, or lack thereof, Defendant intentionally omitted certain results of testing and research to the public, healthcare professionals, and/or the FDA, including the Plaintiff.

148. Defendant had a duty when disseminating information to the public to disseminate truthful information and a parallel duty not to deceive the public and the Plaintiff, as well as their respective healthcare providers and/or the FDA.

149. The information distributed to the public, the FDA, and the Plaintiff by Defendant, including but not limited to reports, press releases, advertising campaigns, television commercials, print ads, magazine ads, billboards, and/or all other commercial media contained material representations of fact and/or omissions.

150. The information distributed to the public, the FDA, and the Plaintiff by Defendant intentionally included representations that Defendant's drug DARVOCET was safe and effective for use as a prescription pain management medication.

151. The information distributed to the public, the FDA, and the Plaintiff, by Defendant intentionally included representations that Defendant's drug DARVOCET carried the same risks, hazards, and/or dangers as other prescription pain management medications.

152. The information distributed to the public, the FDA, and the Plaintiff, by Defendant intentionally included representations that Defendant's drug DARVOCET was more effective for pain management, thereby encouraging the use of DARVOCET in circumstances other than those in which the drug has been approved, over-promises the benefits and minimizes the risk associated with DARVOCET.

153. The information distributed to the public, the FDA, and the Plaintiff, by Defendant intentionally included false representations that DARVOCET was not injurious to the health and/or safety of its intended users.

154. The information distributed to the public, the FDA, and the Plaintiff, by Defendant intentionally included false representations that DARVOCET was as potentially injurious to the health and/or safety of its intended as other prescription pain management medications.

155. These representations were all false and misleading.

156. Upon information and belief, Defendant intentionally suppressed, ignored and disregarded test results not favorable to the Defendant, and results that demonstrated that DARVOCET was not safe as a means of pain management and/or was not as safe as other

means of pain management, including but not limited to other forms of prescription pain management medications.

157. Defendant intentionally made material representations to the FDA and the public, including the medical profession, and the Plaintiff, regarding the safety of DARVOCET, specifically but not limited to DARVOCET not having dangerous and serious health and/or safety concerns.

158. Defendant intentionally made material representations to the FDA and the public in general, including the medical profession and the Plaintiff, regarding the safety of DARVOCET, specifically but not limited to DARVOCET being as safe a means of pain management as other prescription pain management medications.

159. That it was the purpose of Defendant in making these representations to deceive and defraud the public, the FDA, and/or the Plaintiff, to gain the confidence of the public, healthcare professionals, the FDA, and/or the Plaintiff, to falsely ensure the quality and fitness for use of DARVOCET and induce the public, and/or the Plaintiff to purchase, request, dispense, prescribe, recommend, and/or continue to use DARVOCET.

160. Defendant made the aforementioned false claims and false representations with the intent of convincing the public, healthcare professionals, the FDA, and/or the Plaintiff that DARVOCET was fit and safe for use as a prescription pain management medication.

161. Defendant made the aforementioned false claims and false representations with the intent of convincing the public, healthcare professionals, the FDA, and/or the Plaintiff that DARVOCET was fit and safe for use as pain management and did not pose risks, dangers, or hazards above and beyond those identified and/or associated with other prescription pain management medications.

162. That Defendant made claims and representations in its documents submitted to the FDA, to the public, to healthcare professionals, and the Plaintiff that DARVOCET did not present serious health and/or safety risks.

163. That Defendant made claims and representations in its documents submitted to the FDA, to the public, to healthcare professionals, and the Plaintiff that DARVOCET did not present health and/or safety risks greater than other prescription pain management medications.

164. That these representations and others made Defendant were false when made, and/or were made with a pretense of actual knowledge when knowledge did not actually exist, and/or were made recklessly and without regard to the actual facts.

165. That these representations and others, made by Defendant, were made with the intention of deceiving and defrauding the Plaintiff, including their respective healthcare professionals and/or the FDA, and were made in order to induce the Plaintiff and/or her respective healthcare professionals to rely upon misrepresentations and caused the Plaintiff to purchase, use, rely on, request, dispense, recommend, and/or prescribe DARVOCET.

166. That Defendant, recklessly and intentionally falsely represented the dangerous and serious health and/or safety concerns of DARVOCET to the public at large, the Plaintiff in particular, for the purpose of influencing the marketing of a product known to be dangerous and defective and/or not as safe as other alternatives, including other prescription pain management medications.

167. That Defendant willfully and intentionally failed to disclose the material facts regarding the dangerous and serious safety concerns of DARVOCET by concealing and suppressing material facts regarding the dangerous and serious health and/or safety concerns of DARVOCET.

168. That Defendant willfully and intentionally failed to disclose the truth, failed to disclose material facts and made false representations with the purpose and design of deceiving and lulling the Plaintiff, as well as her respective healthcare professionals into a sense of security so that Plaintiff would rely on the representations and purchase, use and rely on DARVOCET and/or that their respective healthcare providers would dispense, prescribe, and/or recommend the same.

169. Defendant, through its public relations efforts, which included but were not limited to the public statements and press releases, knew or should have known that the public, including the Plaintiff, as well as her respective healthcare professionals would rely upon the information being disseminated.

170. Defendant utilized direct to consumer adverting to market, promote, and/or advertise DARVOCET.

171. That the Plaintiff and/or her respective healthcare professionals did in fact rely on and believe the Defendant's representations to be true at the time they were made and relied upon the representations as well as the superior knowledge of pain management and were thereby induced to purchase, use and rely on Defendant's drug DARVOCET.

172. That at the time the representations were made, the Plaintiff and/or her respective healthcare providers did not know the truth with regard to the dangerous and serious health and/or safety concerns of DARVOCET.

173. That the Plaintiff did not discover the true facts with respect to the dangerous and serious health and/or safety concerns, and the false representations of Defendant, nor could the Plaintiff with reasonable diligence have discovered the true facts.

174. That had the Plaintiff known the true facts with respect to the dangerous and serious health and/or safety concerns of DARVOCET, Plaintiff would not have purchased, used and/or relied on Defendant's drug DARVOCET.

175. That the Defendant's aforementioned conduct constitutes fraud and deceit, and was committed and/or perpetrated willfully, wantonly and/or purposefully on the Plaintiff.

176. As a result of the foregoing acts and omissions Plaintiff was caused to suffer and/or are at a greatly increased risk of serious and dangerous side effects including, inter alia, heart arrhythmias, myocardial infarction, other adverse cardiovascular events and/or sudden death, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of developing any of the above named health consequences.

177. As a result of the foregoing acts and omissions the Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental and related expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

178. By reason of the foregoing, Plaintiff has been damaged as against the Defendant in the sum of TEN MILLION DOLLARS ($10,000,000.00).

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against the Defendant on each of the above-referenced claims and Causes of Action and as follows:

1. Awarding compensatory damages to Plaintiff for past and future damages, including but not limited to pain and suffering for severe and permanent personal injuries sustained by the Plaintiff, health care costs, medical monitoring, together with interest and costs as provided by law;

2. Punitive and/or exemplary damages for the wanton, willful, fraudulent, reckless acts of the Defendant who demonstrated a complete disregard and reckless indifference for the safety and welfare of the general public and to the Plaintiff in an amount sufficient to punish Defendant and deter future similar conduct;

3. Awarding Plaintiff reasonable attorneys fees;

4. Awarding Plaintiff the costs of these proceedings; and

5. Such other and further relief as this Court deems just and proper.

Dated: Port Washington, New York
December 9, 2010

Respectfully submitted,

PARKER WAICHMAN ALONSO LLP

By: ______________________________

Matthew J. McCauley (MM-9610)
Six Harbor Park Road
Port Washington, New York 11050-4647
Telephone: (516) 466-6500
Facsimile: (516) 723-4730
Email: mmccauley@yourlawyer.com

Attorneys for Plaintiff Kristine Esposito